

REMARKS/ARGUMENTS

Claims 1-9 are pending, claim 7 having been withdrawn from consideration. By this Amendment, claim 1 is amended. Support for the amendments to claim 1 can be found, for example, in the present specification at page 5, lines 4 to 23 and in original claim 1. No new matter is added. In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

Objection to the Claims

The Office Action objects to claim 1 as including informalities. By this Amendment, claim 1 is amended to obviate the objection. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

Rejection Under 35 U.S.C. §112, First Paragraph

The Office Action rejects claims 1-6, 8 and 9 under the written description requirement of 35 U.S.C. §112, first paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that the recitation in claim 1 the "the at least one starch and the at least one cellulose compound are selected so as to be capable of binding to one another in stable form" is not supported by the present specification. *See* Office Action, page 3. In particular, the Office Action asserts that the present specification fails to disclose selecting a starch and cellulose compound for binding. *See* Office Action, page 3. To obviate the rejection, Applicants amend claim 1 to recite that "the at least one starch and the at least one cellulose compound are bound in stable form." The present specification plainly discloses that the recited starch and cellulose are bound. *See* present specification, page 5, line 4. Moreover, the present specification provides ample description of an exemplary method for

achieving such binding. *See, e.g.*, page 4, lines 4 to 10; Examples. One of ordinary skill in the art would conclude based on this disclosures that Applicants were in possession of presently claimed invention. *See, e.g.*, MPEP §2163.I.

Claims 2-6, 8 and 9 are rejected solely for their dependency from claim 1.

For the foregoing reasons, claims 1-6, 8 and 9 are fully supported by the specification as filed. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph

The Office Action rejects claims 1-6, 8 and 9 as indefinite under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse the rejection.

The Office Action asserts that the recitation of "at least one starch of low molecular weight and high amylopectin content" in claim 1 renders the claim indefinite. *See* Office Action, page 4. By this Amendment, the phrase is deleted to obviate the rejection.

The Office Action asserts that the recitation in claim 1 the "the at least one starch and the at least one cellulose compound are selected so as to be capable of binding to one another in stable form" renders claim 1 indefinite. *See* Office Action, page 4. In particular, the Office Action asserts that the because the phrase does not require the starch and cellulose to be bound, it is not apparent how the phrase limits the invention. *See* Office Action, page 4. To obviate the rejection, Applicants amend claim 1 to recite that "the at least one starch and the at least one cellulose compound are bound in stable form."

Claims 2-6, 8 and 9 are rejected solely for their dependency from claim 1.

For the foregoing reasons, claims 1-6, 8 and 9 are definite. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1, 4, 8 and 9 under 35 U.S.C. §102(b) over U.S. Patent No. 6,419,903 to Xu et al. ("Xu"). Applicants respectfully traverse the rejection.

Claim 1 recites "[a]n An edible film, comprising: at least one starch, the starch being present in an amount of from 20 to 80 % by weight relative to the total weight of the film; at least one cellulose compound selected from the group consisting of hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose and carboxymethylcellulose, the at least one cellulose compound being present in an amount of from 15 to 70 % by weight relative to the total weight of the film; and at least one active substance selected from the group consisting of a cosmetic substance, an aromatic substance, a pharmaceutical substance and a food substance, the at least one substance being present in an amount of from 10 to 50 % by weight relative to the total weight of the film; wherein: the at least one starch and the at least one cellulose compound are bound in stable form; and the film is composed so that the film will dissolve within 10 seconds of contact with saliva " (emphasis added). Xu does not disclose or suggest such a film.

The Office Action asserts that Xu discloses a rapidly dissolvable orally consumable film composition including water soluble, low viscosity hydroxyalkylmethyl cellulose, water dispersible starch and a flavoring agent. *See* Office Action, page 5. The Office Action further asserts that Xu discloses forming a homogenous mixture of starch and cellulose and that, by disclosing such mixture, also discloses that starch is bound to cellulose in stable form. *See* Office Action, page 5. Notwithstanding these assertions, Xu does not anticipate and would not have rendered obvious claim 1.

As correctly pointed out in the Office Action, Xu discloses combining a cellulose and a starch "until the starch was completely dispersed and a homogenous mixture was formed." *See Xu*, column 4, lines 54 to 63 (emphasis added). However, this does not constitute a

disclosure of at least one starch and at least one cellulose compound being bound in stable form, as required by claim 1. A mixture is commonly defined as a "composition of two or more substances that are not chemically combined with each other and are capable of being separated" *See* American Heritage College Dictionary, 2004 (4th ed.), page 892 (emphasis added). One of ordinary skill in the art would not understand based on Xu's disclosure of a homogenous mixture of a cellulose and a starch that the starch and the cellulose are bound in stable form.

Moreover, one of ordinary skill in the art would not understand the cellulose and starch of the composition of Xu to be inherently bound in stable form. The present specification discloses that starch and cellulose can be bound in stable form by successive heating and cooling under agitation. *See, e.g.*, present specification, page 5, lines 4 to 10. This heat treatment causes reaction between hydroxyl groups of the cellulose and hydroxyl and carboxyl groups of the starch. The compositions of Xu are not formed using the procedure followed to bind starch and cellulose in a stable form disclosed in the present specification. Accordingly, one of ordinary skill in the art could not conclude that the cellulose and starch in the composition of Xu would necessarily be bound in stable form. *See* MPEP §2112.IV (citing *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993)) ("[t]he fact that certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of the result or characteristic.").

As Xu fails to disclose or suggest at least one starch and at least one cellulose compound bound in stable form, Xu fails to disclose or suggest each and every feature of claim 1. Moreover, Applicants submit that an edible film including at least one starch and at least one cellulose compound bound in stable form is capable of retaining a greater amount of active substance (*see* present specification, page 5, lines 10 to 14) and dissolving at a faster rate (*see* present specification, Examples) than known edible films.

In addition, Applicants reiterate their remarks in the December 11, 2006 Amendment. In particular, Applicants note that the films of Xu include pre-gelatinized starches, rather than the starch of low molecular weight and high amylopectin content recited in claim 1. *See, e.g., Xu*, column 3, lines 21 to 40. Such pre-gelatinized starches necessarily gelatinize in the presence of saliva in the mouth, and thus adhere to the surface of the mouth when inserted therein. As a result, the films of Xu dissolve in saliva in a time of from about 30 to 40 seconds. *See Xu*, column 2, lines 55 to 58. In the only example in Xu, the dissolution time is 40 seconds. *See Xu*, Table IV. In contrast, the formulation of claim 1 permits dissolution times of 10 seconds or less. *See* present specification, Examples 1 to 4.

The Office Action asserts that Xu's disclosure of dissolution times of "generally in less than 30-40 seconds" (*see* column 2, lines 55 to 58) constitutes a disclosure of the much lower dissolution times encompassed by claim 1. Applicants submit that Xu's disclosure of dissolution times of "less than 30-40 seconds" is merely aspirational, and does not reflect the actual capability of the compositions of Xu. Rather, the capability of the compositions of Xu is reflected in the Examples where dissolution times of from about 30 to 40 seconds are achieved.

As explained, claim 1 is not anticipated by Xu. Claims 4, 8 and 9 depend from claim 1 and, thus, also are not anticipated by Xu. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

#### Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1-6, 8 and 9 under 35 U.S.C. §103(a) over Xu in view of U.S. Patent No. 4,345,032 to Hata ("Hata") and U.S. Patent No. 5,206,026 to Sharik ("Sharik"). Applicants respectfully traverse the rejection.

For the reasons discussed above, Xu fails to disclose or suggest the film of claim 1. Hata is cited for its alleged disclosure of lactobacillus strains having the ability to deodorize foul breath. *See* Office Action, pages 6 to 7. Sharik is cited for its alleged disclosure of films including film-forming polymers such as hydroxyethyl cellulose. *See* Office Action, page 7. However, as Hata and Sharik, like Xu, fail to disclose or suggest a film including an edible film including the particular components, in the particular amounts, and having the particular properties of the edible film of claim 1, the combination of references cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Xu, Hata and Sharik. Claims 2-6, 8 and 9 depend from claim 1 and, thus, also would not have been rendered obvious by Xu, Hata and Sharik. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

#### Conclusion

For the foregoing reasons, Applicants submit that claims 1-9 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.  
Norman F. Oblon

  
\_\_\_\_\_  
Jacob A. Doughty  
Registration No. 46,671

Customer Number  
**22850**  
Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 06/04)